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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,953	05/25/2006	Richard D. Shunnarah	55142.010102	2493

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GREENBERG TRAURIG, LLP
MET LIFE BUILDING
200 PARK AVENUE
NEW YORK, NY 10166

EXAMINER

MARTIN, PAUL C

ART UNIT	PAPER NUMBER
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1657

NOTIFICATION DATE	DELIVERY MODE
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01/25/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

SchindlerB@gtlaw.com
LucasCh@gtlaw.com
NYIPmail@gtlaw.com

Office Action Summary

Application No.

10/552,953

Applicant(s)

SHUNNARAH ET AL.

Examiner

Paul C. Martin

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,7-10,13,15 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,7-10,13,15 and 17-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/13/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 3, 7-10, 13, 15 and 17-19 are pending in this application.

Petition to Correct Filing Receipt

The Applicant's petition to correct filing receipt filed 03/13/07 is acknowledged. The Applicant was sent a missing parts notice, M903, on 05/16/06. The date of Completion of all 35 U.S.C. 371 requirements was on 05/25/06. Therefore the filing date is 05/25/06 and the Petition to Correct Filing Receipt is dismissed.

Election/Restrictions

Applicant's election without traverse of Group II (Claims 1, 3, 7-10, 13 and 17-19) in the reply filed on 12/5/07 is acknowledged. Claim 15 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse.

Claims 1, 3, 7-10, 13 and 17-19 were examined on their merits.

Specification

The disclosure is objected to because of the following informalities:

The Specification should be amended to include the cross-referenced related Applications PCT/US04/11706 filed 04/15/2004 and 60/462,887 filed 04/15/2003.

The specification should include a separate section including a Brief Description of the Drawings.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

(h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f).

A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

The figures included on pages 10 and 12 of the Specification should be removed and provided separately in the Drawings.

The use of the trademarks RABBITCORE™ and COOLRUNNER™ has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Drawings

The drawings are objected to because a description of Figure 3 is lacking from the Brief Description of the Drawings. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended.

The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "30, 32 and 34 of Figure 2" and "20, 22 and 24" in the Specification at Pg. 7, Lines 19-23 have both been used to designate the same support, reagent layer and filtering

layer. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d).

If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New Claim 19 contains the limitation that the filtering layer removes all proteins over 10kDa from the blood however there is no specific support in the Specification as filed for this limitation. The Disclosure teaches a filtering layer (See Paragraph 26), that serum can be filtered through a 0.45 micron prior to enzymatic assays, and separately at paragraph 24 that removal of proteins over 10kDa from serum reduced the inhibition to absorbance, but without indicating how these proteins are removed. Nowhere is it specifically taught that the filtering layer of the test strip removes **all** proteins greater than 10kDa from a blood sample. It is known in the art that a 0.45 micron filter will remove most but not all bacteria from a solution, but no one of skill in the art would use such a filter to remove proteins. It is known in the art to remove proteins larger than 10 kDa with an ultrafiltration membrane with a 10 kDa cutoff, but this is not disclosed. This is a NEW MATTER rejection and Applicant is required to cancel the new matter or amend the claims consistent with the teachings of the disclosure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 7, 8, 10, 13, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwata *et al.* (US 5,912,139).

Iwata *et al.* teaches a test strip comprising a layer capable of having a blood sample applied thereon, wherein the reaction components are applied therein and dried, wherein the layer can be adhered to a second support layer (Column 6, Lines 60-67), wherein the layer can be a membrane filter having a pore size of about 0.1 to 0.5 microns (Column 6, Lines 37-47), wherein the dried layer contains phenylalanine dehydrogenase, gelatin and the buffered enzymatic signaling reagent Alamar Blue/resazurin, wherein the degree of the reaction of the phenylalanine with the phenylalanine dehydrogenase to produce phenylpyruvate (Column 9, Lines 31-65 and Column 10, Lines 1-7 and Table 3) and NADH is measured by the degree of the reaction of the Alamar Blue/resazurin or nitrotetrazolium blue (tetrazolium salt) with the NADH produced by the enzyme/phenylalanine reaction (Column 8, Table 1); that the changes in color tone can be measured with a spectrophotometer, fluorophotometer or the naked eye (Column 1, Lines 25-27), and wherein at least two read measurements of the degree of the reaction are stored graphically (Table 3).

Iwata *et al.* does not teach a medical device comprising a test strip wherein the test strip is comprised of a spreading layer, a filtering layer capable of removing blood cells from a blood sample, means to download at least two results from the medical device, and wherein the spreading layer is in fluid contact with the dry reagent layer.

While Iwata *et al.* does not teach a medical device comprising a test strip, a reading device and a storing device one of ordinary skill in the art would have recognized that this would

result merely from the compilation of the test strip with the spectrophotometer, fluorophotometer or the naked eye and an automated means of storing the measurements which were graphically produced by the method of Iwata *et al.* above.

One of ordinary skill in the art would have been motivated to make this combination as a way of increasing efficiency as all of the components would be complied into one area. The provision of a storing device for storing at least two read measurements and the means to download at least two results from the medical device is a mere automation of the graph of the read measurements of Iwata *et al.* which comprises both downloading or inputting and storing the data. The MPEP teaches:

In re Venner, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958) (Appellant argued that claims to a permanent mold casting apparatus for molding trunk pistons were allowable over the prior art because the claimed invention combined "old permanent-mold structures together with a timer and solenoid which automatically actuates the known pressure valve system to release the inner core after a predetermined time has elapsed." The court held that broadly providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art.).

While Iwata *et al.* does not teach wherein the test strip comprises a spreading layer and a filtering layer, the Examiner deems that the membrane filter layer described by Iwata *et al.* above would perform the same functions as the two separate layers. Namely that the membrane is capable of having a blood sample applied thereon, would inherently therefore be in fluid contact

and based upon the teachings of the instant disclosure which teaches that serum is filtered through a 0.45 micron filter, the filtering membrane of Iwata *et al.* which was 0.1-0.5 microns would obviously perform in a similar manner to remove blood cells.

Regarding the separation of layers of the instant invention vs. the use of a single layer which inherently performs the same functions as taught by Iwata *et al.* the MPEP states:

In re Dulberg, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961) (The claimed structure, a lipstick holder with a removable cap, was fully met by the prior art except that in the prior art the cap is "press fitted" and therefore not manually removable. The court held that "if it were considered desirable for any reason to obtain access to the end of [the prior art's] holder to which the cap is applied, it would be obvious to make the cap removable for that purpose.").

Claims 1, 3, 7-10, 13, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwata *et al.* (US 5,912,139) in view of Steinbach *et al.* (US 4,724,204).

The teachings of Iwata *et al.* were discussed above.

Iwata *et al.* does not teach wherein the dry reagent layer further comprises an electron mediator.

Steinbach *et al.* teaches a method wherein a substrate (lactate) is reacted with a (lactate dehydrogenase) enzyme to form pyruvate and NADH wherein the NADH reacts with nitroblue tetrazolium chloride and the electron mediator PMS form a colorimetric product (Column 2, Lines 5-39).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the phenylalanine detection method of Iwata *et al.* above with the use of an electron mediator as taught by Steinbach *et al.* above because Steinbach *et al.* teaches that PMS was a known hydrogen or electron donor suitable for the detection of NADH in a similar reaction as that of Iwata *et al.* who teaches the reaction of a substrate (phenylalanine) with an enzyme (phenylalanine dehydrogenase) to form phenylpyruvate and NADH which then reacts with nitroblue tetrazolium to form a colorimetric product. The MPEP states:

The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945)

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Leong *et al.* (US 6,555,061 B1) who teaches a multilayer reagent test strip.

Qian *et al.* (US 2003/0211564 A1) who teaches a multilayer reagent test strip.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin
Examiner
Art Unit 1657

01/14/08

/Jon P. Weber/
Jon P. Weber
Supervisory Patent Examiner, 1657